REMARKS/ARGUMENTS

This paper is filed in response to the final Office Action mailed on December 30, 2003.

Claims 1, 2, 4, 10 and 13 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Parker in view of Coneys (U. S. Patent No. 4,657,024). Claim 14 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Parker in view of Coneys and Hopkins. Claims 5, 6, 11 and 12 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Parker in view of Coneys as applied to claims 1, 2, 4, 10 and 13, and further in view of Hopkins.

The present application is directed to an introducer sheath. Introducer sheaths are in widespread use in medical procedures that require percutaneous vascular access. Access may be required, for example, to deliver a fluid to a particular portion of the vasculature, or to deploy an implantable medical device, such as a stent or a catheter, to a deployment site well within the vasculature of the patient.

Many known introducer sheaths incorporate a softer, more flexible, distal tip section onto the distal end of a harder, less flexible, shaft body. Such distal tip sections minimize vessel wall trauma that might otherwise occur if the harder, less flexible distal tip materials were used as the leading end of the sheath. In addition, since the distal tip portion is more easily flexed than the harder proximal shaft portion, the sheath can be more readily guided to a particular site in the vasculature.

Both the main body shaft portion and the distal tip portion of the inventive introducer sheath are formed of FEP. The distal tip portion includes high loadings of radiopaque particles, resulting in a distal tip portion that is distinctly more radiopaque than the main shaft portion. FEP is a favored polymer for use in introducer sheaths due to its low coefficient of friction. Having a low coefficient of friction allows the physician to pass stents, catheters and other interventional devices through the sheath with only a minimum of resistance. In addition, FEP is known to have good flexibility and kink resistance in fairly thin walls, which are important qualities in an introducer sheath that is to be used in accessing remote vascular sites. Although FEP has been widely used in making introducer sheaths, highly loaded radiopaque FEP has not.

In order to properly deploy an implantable medical device to the proper site in the vasculature, it is important for the medical professional to be able to determine the location of the introducer sheath. Accordingly, radiopaque rings are often placed around the outer circumference of the sheath as near the distal end as possible. In this manner, the clinician can observe the position of the sheath under fluoroscopy. Normally, the radiopaque rings are positioned a defined distance, such as ¼ inch, from the distal tip of the sheath. The clinician then estimates the distance from the ring to the end of the sheath to determine where the device should be deployed. It would be preferred, however, for the clinician to be able to observe the exact distal end of the sheath, and not have to estimate such position. In addition, the inclusion of a radiopaque marker ring on a sheath adds substantial rigidity to an otherwise generally flexible portion of the sheath. This rigidity is added at the very portion of the sheath in which it is desired to maintain flexibility.

Some manufacturers have begun to load the short distal tip section with high loadings of a radiopaque agent to make the entire distal tip section radiopaque. As a result, there is little or no need for a radiopaque ring on such sheaths, and the physician can accurately determine the exact position of the distal end of the sheath under fluoroscopy. However, the present inventors are not aware of any such highly loaded radiopaque sections formed of highly loaded FEP. Nor is such a sheath shown in the cited art. This is likely due to a perception that highly loaded sheaths would be difficult to make, and that such highly loaded sheaths would not have sufficient stability to maintain dimensional integrity when used as an introducer sheath.

When a sheath, such as the inventive sheath, includes an elongated sheath body portion and a short radiopaque distal tip portion, it is very important that a reliable bond is formed between such portions. The bonding zone between the tip and the sheath material realizes very high stresses because it is at or very near the area that gets the most bending forces. In addition, relatively large differences in material properties across a short bond zone further concentrate the stresses in the bond zone, making the bond susceptible to failure. The separation of a short tip segment from the remainder of the sheath results in a potentially dangerous embolus free floating in the vasculature. The embolus would eventually lodge somewhere, and form an occlusion to hinder blood flow to tissue. In order to assist in the formation of a reliable bond, some sheaths

utilize the same, or a very similar, polymer in both the shaft and the distal tip portions. An example of such a polymer that is commonly used as both the shaft and distal tip is a polyether block amide such as nylon.

In the inventive sheath, an FEP distal tip is bonded to a shaft body also formed of FEP. Forming both sheath portions from FEP insures a good molecular mix of molten materials, and the formation of a particularly reliable bond. The highly loaded radiopaque material in the tip does not readily flow into and mix with the sheath material during the bonding process.

The application presently contains two independent claims. As claimed in claim 1, the distal tip section of the introducer sheath contains between about 20% and 75% by weight of a radiopaque material. In independent claim 14, the radiopaque particles comprise 50 to 55% of radiopaque tungsten particles.

The distal tip of the catheter described in the primary Parker reference was made of a polyether block amide material, with nylon being a named example. The tip includes high loadings of tungsten to impart radiopacity. The shaft member of the Parker reference comprises an inner layer of PTFE, a wire braid overlaying the PTFE, and an outer layer of polyether block amide. The outer layer of polyether block amide extends distally a greater distance than the inner layer and the braid, such that the tip member is thermally bonded to the polyether block amide portion of the main shaft. However, the Parker reference does not teach the use of FEP as a material for the tip and/or the main shaft body.

The secondary Coneys reference was cited for teaching the use of radiopaque-loaded FEP as the polymeric material in a medical tube. However, Coneys does not teach a highly loaded tube that could be used as a radiopaque tip. In Coneys, layers of pure, virgin FEP define the entire interior and exterior surfaces of the tube to provide smooth surfaces having a low coefficient of friction. An FEP radiopaque layer is fully embedded within the tube wall, and is completely surrounded by layers of pure virgin FEP. See, Fig. 2 of Coneys. The fully embedded, radiopaque layer comprises high amounts (70-80%) of FEP. However, when the radiopaque layer is embedded in the tube as described in the patent, the radiopacity of the tube is

greatly reduced, such that the radiopaque material only comprises between 12-25% of the total weight of the material making up the tube. Col. 3, lines 63-65.

Sandwiching of the pure FEP layers around the highly loaded radiopaque layer in Coneys results in a structure that is much more complicated, and costly, than the arrangement in the claimed invention. In addition, if a sandwiched structure such as the tube taught in Coneys was sliced into relatively short segments for use as a distal tip material, it is likely that the radiopaque material would disengage at some point from the surrounding virgin FEP. In this event, the disengaged radiopaque FEP layer could cause harm to the patient by becoming an embolus that is loose in the vasculature. This possibility is not present in the inventive device, where the radiopaque particles are dispersed throughout the matrix of the distal tip.

The sandwich structure of Coneys results in a radiopaque layer having an effective radiopaque loading of only 12-25%, which is much less than the radiopacity of the distal tip portion of the inventive sheath. As a result, the distinctiveness of the tip portion under fluoroscopy would be much less than that of the tip in the inventive sheath. When working with very small devices, such as stents, it is often important to know *exactly* where the stent is being placed. Indeed, if the device is misplaced the patient fails to achieve the full benefits of the device, and in some cases, can be harmed by the improper placement. When an objective of using such sheaths is to provide a highly radiopaque tip such that interventional devices can be precisely placed in the vasculature, the teaching of Coneys is of little help to the skilled artisan, and would not likely be considered when precise placement is of major concern. In independent claim 1 of the present application, the loading of radiopaque material is between about 20 and 75% by weight of radiopaque material. In independent claim 14, the radiopaque loading is between about 50 and 55% by weight. With such high loadings dispersed throughout the sheath, more precise placements may be made.

The present invention provides a very simple, cost effective FEP introducer sheath that has a highly loaded radiopaque distal tip securely bonded to the main shaft body. The cited combination of the Parker and the Coneys references fails to teach or even suggest such a sheath. As stated, Parker does not disclose or suggest the use of low friction FEP sheaths. A skilled artisan, with knowledge of both Parker and Coneys, would believe that it was necessary to fully

embed a highly loaded FEP layer in pure FEP if it was desired to employ a highly radiopaque layer in an FEP introducer sheath. Coneys offers no suggestion of any other manner of including the radiopaque layer, and clearly teaches away from the use of a single, highly loaded FEP segment as utilized in the inventive sheath. Indeed, an artisan having knowledge of the Coneys patent might refrain from using FEP altogether, out of concern that the sheath would have insufficient radiopacity for use in remote vascular passages.

Contrary to the teachings of the cited references, the sheath of the present invention achieves radiopacity in a very satisfactory manner. A low friction FEP radiopaque tip is bonded to an FEP main shaft body. The radiopaque tip does not comprise a radiopaque layer in the sheath that is subject to disengagement from the remainder of the distal tip. Rather, the radiopaque particles of the inventive sheath are fully dispersed throughout the tip. Since the radiopaque material can be loaded at high levels in the distal tip section, the physician can clearly detect the distal end of the sheath. Since the distal tip and the shaft body in the inventive sheath are both made of FEP, a very reliable bond can be formed therebetween.

This arrangement is much simpler, less costly, and radiographically superior to that taught in cited combination of references.

Thus, for the reasons provided above, Applicants submit that claim 1 and dependent claims 2, 4, 10 and 13 are allowable over Parker in view of Coneys.

Claim 14 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Parker (270) in view of Coneys and Hopkins, and claims 5, 6, 11 and 12 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Parker in view of Coneys as applied to claims 1, 2, 4, 10, 13 and 16, and further in view of Hopkins. The Hopkins reference was cited for teaching the use of radiopaque materials such as tungsten in a catheter, and for teaching that particles can be as small as 0.9 microns, which, according to the Examiner, suggests that they can be any size larger than 0.9. The Hopkins patent is directed to a compliant marker band that is heat shrunk over a catheter or sheath, thus eliminating the need for heat or adhesive bonding. Col. 2, lines 34-36; Col. 3, lines 15-17. The marker band surrounds the external surface of the catheter or sheath and includes a radiopaque material such as tungsten.

By using a marker band, Hopkins teaches away from the present invention by employing technology that the present inventors desire to avoid. The use of a marker band that is heat shrunk or otherwise positioned over a sheath increases the thickness of the sheath wall, and thereby imparts a certain amount of rigidity to the sheath. In addition, the use of a radiopaque marker band forces the operator to estimate the precise location of the distal tip of the device. In the present invention, the radiopaque marker <u>is</u> the distal tip, thereby eliminating this guesswork. Applicants do not dispute that highly radiopaque marker bands are known in the art. However, the Hopkins reference does not teach or suggest the use of FEP in an introducer sheath for the purposes described, nor does it teach or suggest that a distal tip can function as a radiopaque marker. In addition to the foregoing, one skilled in the art would not likely make the cited combination, since Hopkins also teaches away from a purpose of the present invention, namely the use of a highly loaded distal tip, instead of a marker band. Thus, Applicants respectfully submit that claims 5, 6, 11, 12 and 14 are allowable in view of the cited combination.

Based upon the remarks provided hereinabove, Applicants respectfully submit that all claims 1, 2, 4-6 and 10-14 are allowable over the combination of references discussed hereinabove. Accordingly, Applicants respectfully request that the Examiner reconsider the previous rejections in view of these claims. If the Examiner believes that prosecution of this application may be expedited by way of a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,

Lawrence A. Steward
Atty. No. 32,309

LAS/cbw

BRINKS HOFER GILSON & LIONE
One Indiana Square, Suite 1600
Indianapolis, Indiana 46204
Phone: (317) 636-0886
Fax: (317) 634-5701